

**REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

**I. CLAIM STATUS & AMENDMENTS**

Claims 1-3 and 5 were pending in this application when last examined and stand rejected.

Support for the amendment to claim 3 can be found in the disclosure, for example, at page 4, lines 9-14, page 5, line 6 and in claims 1 and 3 as filed. No new matter has been added.

Claim 2 has been canceled without prejudice or disclaimer thereto. Applicants reserve the right to file a continuation or divisional application on any cancelled subject matter.

Claim 1, 3 and 5 are pending upon entry of this amendment

**II. OBVIOUSNESS REJECTION**

In item 4 on pages 2-13 of the Office Action, claims 1, 3 and 5 were newly rejected under 35 U.S.C. § 103(a) as obvious over Yu et al. (Genome Res., vol. 7, no. 4, pp. 353-358, 1997) (of record as AF052135) in view of Hutchinson et al. (Nucleic Acids Research, vol. 20, no. 13, pp. 3453-3462, 1992), Solovyev et al. (Nucleic Acids Research, vol. 22, no. 24, pp. 5156-5163, 1994) and Eberhard Passarge (Color Atlas of Genetics, Georg Thieme Verlag Stuttgart, New York, Thieme Medical publishers, Inc. New York, pp. 49, 1995).

This rejection is respectfully traversed.

Amended claim 3 calls for An isolated polynucleotide encoding a human protein hAMSH having the amino acid sequence of SEQ ID No. 1, which is a signal transduction molecule for cell proliferation, wherein the polynucleotide consists of the nucleotide sequence of SEQ ID NO 2.

As acknowledged at pages 3-4 of the Office Action, Yu et al. (AF052135) only disclose a cDNA clone that contains the 1st-1356th nucleotide sequence of SEQ ID No: 2 of the instant

application. The 107th-1462nd nucleotide sequence of Yu (AF052135) is identical to the 1st-1356th nucleotide sequence of SEQ ID No: 2. The Office contends that Yu et al. (AF052135) teach a polynucleotide that is 100% identical to SEQ ID NO: 2 “over a span of” 1356 base pairs. The Office notes that the polynucleotide is “contained in” a vector, and that the polynucleotide of Yu et al. (AF052135) “contains” the polynucleotide of SEQ ID NO: 2.

Moreover, as acknowledged by the Office, Yu et al. (AF052135) does not disclose the polypeptide of SEQ ID 1, nor does it disclose which specific fragment of the polynucleotide encodes the peptide. Yu (AF052135) never discloses the coding region for a protein. The Office even acknowledges that Yu et al. (AF052135) does not disclose the start or stop coding regions of the protein. Yu et al. (AF052135) also does not disclose the functionality of the protein of the present invention.

Nonetheless, the Office argues that specific polynucleotide sequence encoding the polypeptide and the polypeptide itself would have been readily apparent to the skilled artisan based on the sequence and the knowledge in the art. The Examiner argues that it would have been obvious that three possible polypeptides can be translated “using the polynucleotide of SEQ ID NO: 2.” See the top of page 4.

However, how can the skilled artisan “use the polynucleotide of SEQ ID NO: 2”, if such sequence is not disclosed in the cited prior art. Again, as acknowledged by the Office, Yu et al. (AF052135) does not disclose or suggest a polynucleotide consisting of SEQ ID NO: 2 as claimed. Yu et al. (AF052135) only discloses a larger polynucleotide containing it. Since Yu et al. (AF052135) does not disclose SEQ ID NO: 2, it is illogical to assert that the skilled artisan could predict that three possible polypeptides can be translated “using the polynucleotide of SEQ ID NO: 2.” Instead, they would have to use the large sequence of Yu et al. containing the polynucleotide of SEQ ID NO: 2

Again, amended claim 3 is limited to a polynucleotide that consists of the nucleotide sequence of SEQ ID NO 2. Such language excludes the larger sequence in Yu et al. (AF052135) containing such sequence.

Nonetheless, the Office argues that it would have been obvious to use the polynucleotide in Yu et al. (AF052135) to determine and isolate possible DNA fragments encoding the three possible splice variants encoding the polypeptide of SEQ ID NO: 1 of the invention. See the top of page 12 of the Action. The Office asserts that the “ordinary artisan would have been motivated to identify the possible proteins encoded by the polynucleotide disclosed of Yu to determine the functionality encoded by the polynucleotide”, because “a piece of DNA is useless if it cannot be associated with a function.”

In reply, it is respectfully submitted that the mere existence of a DNA sequence is not a suggestion to investigate the sequence to identify a particular sequence contained therein that may encode a protein. To suggest otherwise is basically the same as saying that all proteins are obvious, if a larger DNA sequence exists that may encompass the specific sequence encoding the protein. Again, Yu et al. (AF052135) fail to disclose or suggest an hAMSH protein, let alone one having the amino acid sequence of SEQ ID No. 1. Moreover, Yu et al. (AF052135) does not disclose an amino acid sequence. In this regard, Yu et al. (AF052135) never discloses any protein encoded by the larger DNA sequence disclosed therein. Yu et al. (AF052135) only disclose a nucleic acid, and not a protein. Also, Yu et al. (AF052135) fail to disclose the function of the protein as a signal transduction molecule for cell proliferation. Accordingly, what motivation is there in the cited references for doing so other than the blanket assertion by the Office that “a piece of DNA is useless if it cannot be associated with a function.”

Consequently, Yu et al. (AF052135) fail to disclose or suggest the specific polynucleotide consisting of SEQ ID No: 2, encoding the hAMSH having the amino acid sequence of SEQ ID NO: 1 of the claims.

Furthermore, Yu et al. (AF052135) indicate that “All 65 cDNA clone sequences described in this paper have been submitted to the GenBank data library under accession nos. U79240-U79304.” See page 353, below the Abstract. Attached are a copy of U79240 and U79241 as an example of the submitted data. Please note that the submitted cDNA sequences are “partial” sequences. This means that the cDNAs do not encode a full length protein. More precisely, among the 65 clones, 17 clones are partial, 14 clones are complete (i.e., encoding full length protein), and the remaining 34 clones are mRNA sequences only to which partial or complete is not designated. Applicants respectfully submit that coding region for the remaining 34 clones was not determined.

Human clone 23625 is not contained in U79240-U79304, but it was submitted to GenBank under accession No. AF052135, which shows mRNA sequences only, similar to the remaining 34 clones.

Only mRNA sequences are shown for the remaining 34 clones of U79240-U79304 and AF052135. On page 4 of the Action, the Office asserts that a polypeptide can be determined from the positions of the start codon and stop codon of mRNA sequences. If this was correct, then any coding regions for the 34 clones and AF052135 might be easily determined. But Yu et al. (AF052135) did not do so. Again, please see the mRNA sequences of the attached U79240 and U79241. Even though the mRNA sequences contain some start codon (ATG), Yu et al. determined that the sequences were “partial.” In other words, contrary to the Office’s position, it would not be obvious to determine the DNA sequence encoding the polypeptide of the present invention.

As is well known in the art field, it is not easy to clone a complete cDNA fragment from mRNA molecules. The skilled artisan knows that the human clone 23625 (AF052135) was isolated by the same process as those of U79240-U79304. As such, the skilled artisan would understand that the cloning method in Yu et al. is inadequate for cloning “complete cDNA.”

For these reasons, it is clear that Yu et al. (AF052135) fail to disclose or suggest the specific polynucleotide consisting of SEQ ID No: 2, encoding the hAMSH having the amino acid sequence of SEQ ID NO: 1 of the claims. Moreover, it would not have been obvious to identify the coding region of the DNA and then obtain the hAMSH having the amino acid sequence of SEQ ID NO: 1.

In view of the above, the above-noted 103(a) obviousness rejection is untenable and should be withdrawn.

### **III. ANTICIPATION REJECTION**

In item 5 on pages 14-24 of the Action, claims 1, 3 and 5 were newly rejected under 35 U.S.C. 102(a) as being anticipated by Tanaka et al. (*J. Biol. Chem.*, vol. 274, no. 27, pp. 19129-19135, July 2, 1999 and GenEmbl sequence Accession U73522 of the clone contained therein). The Office has asserted that Tanaka et al. (U73522) discloses the polynucleotide AMSH of SEQ ID NO: 2 of the present invention.

This rejection is respectfully traversed on the basis that Tanaka et al. (U73522) is not available as prior art against the present invention.

The instant application is a 371 of PCT/JP99/06309, filed November 12, 1999, which claims foreign priority to Japanese patent application No. 1998-322674, filed November 12, 1998. Kindly note that the Office has previously acknowledged the foreign priority claim and receipt of certified copies of the foreign priority document. See item 12(a)1 on page 1 of the Office Action of December 10, 2003.

Thus, Applicants' November 12, 1998 priority date precedes the July 2, 1999 publication date of Tanaka et al. (U73522). Therefore, Tanaka et al. (U73522) is not available as prior art against the present invention. For this reason, the rejection is improper and should be withdrawn.

#### **IV. WRITTEN DESCRIPTION REJECTIONS**

In item 7 on pages 24-27 of the Action, claims 2 was newly rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

For the sole purpose of expediting prosecution and without intending to acquiesce to the rejection, the present amendment cancels claim 2, thereby obviating this rejection.

In items 8-9 on pages 27-28, claim 3 was newly rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. This is a new matter rejection. The amendment filed December 7, 2005 is also objected to for adding new matter. The Office has argued that the species of the polynucleotide which consists of the nucleotide sequence from the 11<sup>th</sup> to the 1285<sup>th</sup> nucleotide of SEQ ID No.2 constitutes new matter.

For the sole purpose of expediting prosecution and without intending to acquiesce to this rejection, the objected language has been removed from claim 3. Thus, the present amendment overcomes this rejection.

#### **V. PATENTABLE SUBJECT MATTER**

In item 10 on pages 28-29 of the Action, claim 3 was newly rejected under 35 U.S.C. 101 on the basis that the claimed invention is directed to non-statutory subject matter for lacking language indicating the polynucleotide is isolated or purified from nature.

The present amendment overcomes this rejection by amending the claim to recite an “isolated” before “polynucleotide” as suggested by the Office. As such, the amended claim no longer reads on a product of nature.

#### **VI CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

Attorney Docket No. 2001\_0572A  
Serial No. 09/831,452  
August 31, 2007

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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By:



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August 31, 2007

Attorney Docket No. 2001\_0572A  
Serial No. 09/831,452  
August 31, 2007

**ATTACHMENTS:**

1. Copy of U79240, U79241, and AF0523135 submitted in Yu et al. .



# Nucleotide

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 sequence all but gene, CDS and mRNA features

Range: from begin

to end

 Reverse complemented strand

Features:

 SNP

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1: U79240. Repons Human serine/thre...[gi:1710185]

Links

Features Sequence

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**ACCESSION** U79240  
**VERSION** U79240.1 GI:1710185  
**KWORDS**  
**SOURCE** Homo sapiens (human)  
**ORGANISM** Homo sapiens  
Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;  
Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.  
**REFERENCE** 1 (bases 1 to 1876)  
**AUTHORS** Andersson, B., Wentland, M.A., Ricafrente, J.Y., Liu, W. and Gibbs, R.A.  
**TITLE** A 'double adaptor' method for improved shotgun library construction  
**JOURNAL** Anal. Biochem. 236 (1), 107-113 (1996)  
**MEDLINE** 96207227  
**REFERENCE** 2 (bases 1 to 1876)  
**AUTHORS** Yu, W., Andersson, B., Worley, K.C., Muzny, D.M., Ding, Y., Liu, W.,  
Ricafrente, J.Y., Wentland, M.A., Lennon, G. and Gibbs, R.A.  
**TITLE** Large Scale Concatenation cDNA Sequencing  
**JOURNAL** Unpublished  
**REFERENCE** 3 (bases 1 to 1876)  
**AUTHORS** Yu, W. and Gibbs, R.A.  
**TITLE** Direct Submission  
**JOURNAL** Submitted (22-NOV-1996) Molecular and Human Genetics, Baylor  
College of Medicine, One Baylor Plaza S930, Houston, TX 77030, USA  
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**ORIGIN**

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Send to
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Refresh

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Links

Features Sequence

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**VERSION** AF052135.1 GI:3360444  
**KEYWORDS** FLI\_CDNA.  
**SOURCE** Homo sapiens (human)  
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**REFERENCE** 1 (bases 1 to 1462)  
**AUTHORS** Andersson, B., Wentland, M.A., Ricafrente, J.Y., Liu, W. and Gibbs, R.A.  
**TITLE** A 'double adaptor' method for improved shotgun library construction  
**JOURNAL** Anal. Biochem. 236 (1), 107-113 (1996)  
**PUBMED** 8619474  
**REFERENCE** 2 (bases 1 to 1462)  
**AUTHORS** Yu, W., Andersson, B., Worley, K.C., Muzny, D.M., Ding, Y., Liu, W., Ricafrente, J.Y., Wentland, M.A., Lennon, G. and Gibbs, R.A.  
**TITLE** Large-scale concatenation cDNA sequencing  
**JOURNAL** Genome Res. 7 (4), 353-358 (1997)  
**PUBMED** 9110174  
**REFERENCE** 3 (bases 1 to 1462)  
**AUTHORS** Yu, W., Sarginson, J. and Gibbs, R.A.  
**TITLE** Direct Submission  
**JOURNAL** Submitted (05-MAR-1998) Molecular and Human Genetics, Baylor College of Medicine, One Baylor Plaza S930, Houston, TX 77030, USA  
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**ORIGIN**

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